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69. PHARMACEUTICAL WASTE DISPOSAL IN CROATIA

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ABSTRACT

In the framework of secured significant financial support provided by the World Bank the implementation of project that will solve the problem of large quantity of unusable or outdated pharmaceutical materials, donated during the period of war, has started in March 2001 in Croatia. Expired pharmaceuticals are scattered across the country in about 250 locations, of which 25 sites contain over 70% of the total quantity. Present estimates of quantities are 3500 tones of pharmaceutical materials mixed with other medical supplies. As the large volume of waste has been currently stored in a variety of different conditions, and occupied in the unsatisfactory and disorderly manner in many storage places, the first step necessary to be undertaken is sorting and repackaging of the stockpiles to reduce the volume of waste that requires special treatment for disposal. Waste should be put into safe containers that can be sealed, and are suitable for transportation to a final disposal facility. Project implementation requires the expertise and organized human resources, time, suitable treatment facility and other resources to complete all the steps necessary to remove this one-time accumulation of unwanted materials. Pharmaceutical waste that has represented a hazard to segments of population and the environment for many years would be now disposed of using methods consistent with international environmental best practice and standards and so far gained experiences.

INTRODUCTION - chronology of preparatory activities for project launching

Project of "Pharmaceutical Waste Disposal in Croatia" implementing from March 2001 in Croatia is the result of extensive years-long preparation. Its final implementation has been requested by the World Bank, which put stringent requirements relating to all project activities. Large quantities of expired pharmaceuticals, as a result of unused or unusable humanitarian donations received during the war period in Croatia, have been stored about ten years in inadequate locations all over Croatia (railway stations, empty hospital buildings, various shelters, health care institutions...), waiting in such conditions for final disposal. Due to frequent break-ins into temporary warehouses and several fires, which broke out on several sites expired pharmaceuticals pose a potential hazard to environment and human health. In addition, they occupy large parts of serviceable storage spaces in almost all the sites in Croatia. Already in 1997, APO Ltd. initiated and performed a great number of preparatory project activities with an aim to establish and implement final activities for permanent pharmaceutical waste disposal in the country. Previous APO's reference activities undertaken from the own APO funds are:

1. *Reliable and precise determination of pharmaceutical waste quantities from donation on the locations of Splitsko-Dalmatinska and Šibensko-Kninska Counties, August 1997;*
2. *Preparation of "Working Protocol - Guidelines for Pharmaceutical Waste Sorting and Repackaging Aiming at Reducing Waste Quantities", May 1998, applicable for every location in Croatia;*
3. *WHO representative mission organization and drafting project proposal: "Recovery and Disposal of Expired Pharmaceuticals in Croatia, Outline proposal for collaborative involvement, July 3, 1998";*

4. Preparation of *"Programme for the Entire Pharmaceutical Waste Sorting and Repackaging in Split"*, November 1998.

Records on received quantities and types of pharmaceuticals were not kept systematically on all sites and there was no real data on waste quantities and types requiring final disposal. Since every site in Croatia is specific, in co-operation with the World Health Organisation (WHO), which has successfully realized similar activities in Mostar, APO Ltd. accomplished the expert detailed characterization for specific sites in Split and Šibenik. These sites surveys were chosen for assessing the stockpiles of great quantities of expired pharmaceuticals and medical supplies/equipment, which were stored in some 20 railway wagons that were kept without adequate surveillance. According to the assessments made, the overall quantity of expired pharmaceuticals have shown that only on the sites in Split and Šibenik it could be expected about 250 tons of expired pharmaceuticals. For their final disposal it would have been necessary to undertake the previous necessary step, sorting and repackaging, i.e. conditioning in order to minimize the waste volume and quantities requiring special treatment for final disposal.

At the beginning of 1998, Croatian Institute for Toxicology performed the first extensive survey of all sites in Croatia and assessed quantities, following the methodology developed during characterization of the Split and Šibenik locations. During the survey, it was identified and registered 250 warehouses, but most of the waste was stored in approximately 20 big stocks, situated besides important hospitals. At that time, it was roughly estimated that cca 3 500 tons of various donated pharmaceutical and other medical supplies required final disposal. Further, it was estimated that after previously undertaken separation (sorting and repackaging) only approx. 2 500 tons would refer to expired pharmaceuticals, and the rest of approx. 1 000 tons would relate to unused disposal consumable material (gauze, bandages, needles, sharps, syringes, catheters), homeopathic and herbal preparations, diet products and packaged food items, and other medical supplies and equipment (beds, various orthopedic accessories and wheel chairs, instruments, detergents, antiseptics...). Different types of chemical wastes were identified on various sites also requiring special treatment. General characterization of sites in Croatia has shown that only a few number of sites have followed Guidelines previously issued by Ministry of Health and kept the waste properly separated (for example - stocks in Karlovac and Pula). In the remaining stocks, waste from donation was only partially separated or mixed, and in such a state that it was not possible to assess more reliable estimate of expected quantities.

In July 1998, the mission of WHO representative with representatives of authorized institutions in Croatia (Ministry of Health, State Directorate for the Environment, Croatian Institute for Toxicology, County Office for Work, Health Care and Social Welfare in County Splitsko-Dalmatinska, Croatian railways, Center for the Receipt and Distribution of Drugs and Medical Supplies, and APO Ltd.) developed the outline proposal as a background for further guidance and the beginning of more concrete project implementation. Expert mission considered that the pharmaceutical waste stockpiles in Croatia should be dealt with as a matter of urgency and that the problem is definitely solvable within approx. one year because there is enough expertise to undertake the necessary work. It was concluded that the problem has to be systematically considered at the state level, with the approach requiring good organization and harmonized programme of final disposal.

In September 1998, in organization of County Splitsko-Dalmatinska, the pilot project in two railway wagons in Split was implemented in compliance with the WHO recommendations. The aim of the pilot project was to evaluate the parameters of necessary

labor, time, ratio of reduced waste volume and quantities, and necessary cost serving as a basis for project implementation at the state level.

Although a small number of health care institutions successfully managed the quantities of expired pharmaceuticals through their internal funds, the majority of health care institutions and authorized institutions could not have been able to secure funds for disposal of all estimated quantities. For this reason, the Ministry of Health entered into negotiations with the World Bank, during 1999.

METHODOLOGY OF PROJECT IMPLEMENTATION - basic project data

Funding of the project estimated at approx. USD 3.8 million was provided at the end of 2000, within the loan of the World Bank supporting on Health System Project in the Republic of Croatia. Croatia was obliged to fulfill all the required prerequisites for financial support defined by the Loan Agreement, in compliance with internationally most acceptable environmental methods and recommendations of the World Bank.

The World Bank accepted to finance the implementation of defined project activities: pharmaceutical waste separation and sorting from medical supplies at 25 priority sites with prior consolidation of pharmaceutical wastes from out-of-site locations, transport from 25 defined sites throughout Croatia, incineration of delivered waste in "PUTO" incinerator (as the only incineration plant in Croatia fulfilling all the requirements with respect to environmental and industrial safety, and necessary capacity), and disposal of the resultant fly ash.

Warehouses, as defined sites, were selected primarily on the criteria: to keep relatively large quantities of pharmaceutical waste, to have good road connection with Zagreb, to be geographically close to small warehouses, to have adequate sanitary conditions for sorting on the site, to provide protection against adverse weather conditions, to provide enough space for sorting activities on the site. Secondary criteria for selection of defined locations were applied for areas in which the pharmaceutical waste was in a poor condition: warehouses affected by fire, as the ones in Split and Zadar, and warehouses exposed to adverse weather conditions and burglaries, as the case was with the railway wagon in Split.

In compliance with the World Bank rules, the international tender was invited for the selection of the company to perform sorting and transport activities to the incinerator "PUTO". Tender has stringently defined a great number of requirements that the eligible company must submit and fulfill in order to be entrusted with project activities (for example: necessary authorities for performing hazardous waste collection; previous work experience in hazardous waste organization in the past three years; qualification and experience for technical personnel proposed for work including health fitness; technical documentation for every vehicle forecasted to transport; performance security in the amount of 5% of the contract price during the whole period of project implementation, etc.).

APO Ltd. and PUTO Ltd. are two companies under contractual obligations for envisaged four project phases. Project implementation is time scheduled for a total period of nine months.

In the first phase, sorting activities have included separation of medical equipment from pharmaceutical waste, and large packaging material from the pharmaceuticals. Following sorting, waste is disposed of at the closest local municipal disposal facility, close to the site where sorting activities are performed.

In the second phase, separated pharmaceutical waste is sorted and prepared for transportation to the incinerator as a dry waste capable of packing into cardboard boxes and as a liquid waste, solid wet waste, ampoules, vials, needles and sharps, which should be stored and transported in plastic or metal barrels hermetically sealed.

Sorting and transport of waste in sealed pressurized gas containers, cytostatics and narcotics is performed under special surveillance and with separate labeling. Each sorted box or barrel should be sealed shut, labeled, marked according to the waste category and weight, number of site and palette, and movable by forklift. Personnel in charge of sorting should have toxicologically educated and be properly protected during sorting by proper worker attire.

Transport activities have included pharmaceutical waste transport from defined sites to the incinerator, and transport organization of other sorted materials to the closest local municipal disposal site. The vehicles should be equipped and labeled in compliance with ADR, and labeled and secured during transport in compliance with the recommendations of Croatian Institute for Toxicology. Procedures should be defined in case of an accident. Drivers should be educated pursuant to legal provisions defining transportation of hazardous chemicals. For every single transport the written permission should be issued by County Office for Work, Health Care and Social Welfare. During the loading of each vehicle responsible person from local authority (local sanitary inspector) must be present. After the loading is complete on the cargo compartment of the vehicle, the official seal is put that can be removed exclusively after the official weighing in the incinerator. After the last quantities of waste are transported to the incinerator, and other sorted materials are disposed of, the site has to be cleaned and decontaminated.

This project requires keeping the following records: weekly reports on performed sorting, reports on each shipment of pharmaceutical/other sorted materials, and monthly sorting and transport reports that are submitted to the Ministry of Health (World Bank) and Croatian Institute for Toxicology. All the activities relating to the implementation of this international project are performed under surveillance of the WB/WHO, Ministry of Health, Croatian Institute for Toxicology, Department for sanitary inspection, respecting all safety measures relating to environment, health of humans and relevant regulations of the Republic of Croatia, and in the co-operation with County Office for Work, Health Care and Social Welfare. Ministry for Environmental Protection is involved in the project within its competence

STATUS OF PROJECT IMPLEMENTATION

Project implementation has started at the beginning of March 2001. As a co-coordinator, APO Ltd. with its four subcontracting companies (Dezinsekcija d.o.o. of Rijeka, Cian d.o.o. of Split, ZIV Trade of Zagreb and MC Čišćenje of Sisak) is performing in a harmonized manner sorting and transport activities according to contractual project time schedule. The first activities were completed on priority sites in Dalmatian area, prior to this year tourist season and taking into account sites in bad conditions. In this way, sorting and transport activities are conducted from different part of Croatia simultaneously. It is anticipated that the project will be finished even before the term stipulated by the contract because by the middle of September activities have been completed on almost 20 sites. Over 1200 tons of hazardous pharmaceutical waste has been accepted by "PUTO" out of which some 85% of waste have been incinerated.

Experience gained during this project implementation in the Republic of Croatia, covering all its phases and all the partners involved, will for sure serve as positive guidelines for establishment of the successful health care waste management system.

KEYWORDS

Outdated pharmaceuticals, pharmaceutical waste disposal